

## REMARKS

Claims 2-3, 6-28, and 30-31 constitute the pending claims in the present application. Claims 1-2, 4-18, 21, and 29 were elected with traverse. Applicants will cancel non-elected claims upon indication of allowable subject matter. Please cancel claims 29 and 33-35 without prejudice. Claims 2, 6-10, 21, and 31 have been amended. Support for the amendments is found throughout the specification. No new matter has been added. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

Applicants note with appreciation that the amendments put forth in Paper 20 (4/8/03) have been entered in full.

### Claim rejections under 35 U.S.C. 112, first paragraph

Claims 2, 6-18, 21, 29, 31, and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to enable one of skill in the art to practice the claimed invention. Applicants traverse these rejections to the extent that they are maintained in light of the amended claims.

The Examiner acknowledges that the specification is enabling for methods of suppressing or promoting thymic T-cell maturation comprising administering a polypeptide at least 100% identical to the N-terminal auto-proteolytic fragment of a hedgehog polypeptide, wherein said peptide binds a naturally occurring patched protein. However, the Examiner asserts that the specification does not reasonably provide enablement for the broad scope of suppressing or enhancing the immune function or immune system of an animal, nor for modulating T-cell maturation other than in the thymus (e.g., peripheral T-cell maturation), nor for any form of therapy, and nor for the suppression of promotion of T-cell maturation comprising the administration of a hedgehog agonist thereof other than a polypeptide at least 100% identical to the N-terminal auto-proteolytic fragment of a hedgehog polypeptide or an antagonistic antibody that binds thereto.

Applicants reiterate the arguments of record and contend that the specification is enabling for the claimed methods. The application amply teaches the use of hedgehog agonists/antagonists in suppressing or enhancing the immune function/system of an animal. Given the teachings of

the specification and the knowledge in the art at the time the application was filed, one skilled in the art would readily practice the claimed invention without undue experimentation.

Nevertheless, solely to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended independent claims 2 and 31 to define the structure and function of the hedgehog agonists and to clarify their use in suppressing thymic T cell maturation. The amendments are fully supported by the original specification and by the evidence obtained since the filing of the present application (see Exhibit 1 in the previous response). Applicants submit that the amendments are not made in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope.

In view of the arguments and amendments presented above, Applicants submit that all pending claims as amended fully comply with the enablement requirement. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph, are respectfully requested.

#### Claim rejections under 35 U.S.C. 112, first paragraph

The Examiner maintains the rejection of claims 2, 6-9, 11-18, 21, 29, 31, and 33-35 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants traverse this rejection to the extent that it is maintained over the amended claims.

Applicants reiterate the arguments made of record and contend that the application, as filed, provides ample support for a wide range of hedgehog agonists/antagonists. One of skill in the art could easily envision the polypeptides and small molecules of the invention. Applicants contend that claims directed to hedgehog agonists are well supported by the specification.

Nevertheless, solely to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended claims 2, 7-10, 21, 31, and 33-35 to more particularly point out the hedgehog agonists for use in the subject methods. Applicants submit that the amendments are not made in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope.

In view of the arguments and amendments presented above, Applicants submit that all pending claims as amended fully comply with the written description requirement. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph, are respectfully requested.

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims as amended are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Respectfully Submitted,

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